

**THE OFFICE OF INSPECTOR GENERAL'S
COMPLIANCE PROGRAM GUIDANCE
FOR CLINICAL LABORATORIES**

AUGUST 1998

TABLE OF CONTENTS

	<u>Page</u>
I. Introduction	1
A. Benefits of a Compliance Program	3
B. Application of Compliance Program Guidance	4
II. Compliance Program Elements	5
A. Written Policies and Procedures	7
1. Standards of Conduct	7
2. Medical Necessity	8
a. Requisition Design	9
b. Notice to Physicians	9
c. Physician Acknowledgments	10
d. Use of Advance Beneficiary Notices	10
e. Test Utilization Monitoring	11
3. Billing	12
a. Selection of CPT or HCPCS Codes	12
b. Selection of ICD-9-CM Codes	12
c. Tests Covered by Claims for Reimbursement	13
d. Billing of Calculations	13
e. Reflex Testing	14
4. Reliance on Standing Orders	14
5. Compliance with Applicable HHS Fraud Alerts	14
6. Marketing	15
7. Prices Charged to Physicians	15
8. Retention of Records	16
9. Compliance As An Element of a Performance Plan	16
B. Designation of a Compliance Officer and a Compliance Committee	17
1. Compliance Officer	17
2. Compliance Committee	19
C. Conducting Effective Training and Education	20
D. Developing Effective Lines of Communication	22
1. Access to the Compliance Officer	22
2. Hotlines and Other Forms of Communication	23
E. Enforcing Standards Through Well-Publicized Disciplinary Guidelines	24
1. Discipline Policy and Actions	24
2. New Employee Policy	25
F. Auditing and Monitoring	26

G.	Responding to Detected Offenses and Developing Corrective Action Initiatives	30
1.	Violations and Investigations	30
2.	Reporting	31
III.	Conclusion	34

I. INTRODUCTION

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) continues in its efforts to promote voluntarily developed and implemented compliance programs for the health care industry. The following compliance program guidance is intended to assist clinical laboratories in developing effective internal controls that promote adherence to applicable federal and state law, and the program requirements of federal, state, and private health plans.¹ The adoption and implementation of voluntary compliance programs significantly advance the prevention of fraud, abuse, and waste in the clinical laboratory industry while at the same time further the fundamental mission of all health care providers, which is to provide quality services and care to patients.

Within this document, the OIG intends to provide first, its general views on the value and fundamental principles of clinical laboratory compliance programs, and second, specific elements that each clinical laboratory should consider when developing and implementing an effective compliance program. While this document presents basic procedural and structural guidance for designing a compliance program, it is not in itself a compliance program. Rather, it is a set of guidelines for consideration by a clinical laboratory interested in implementing a compliance program. The recommendations and guidelines provided in this document must be considered depending upon their applicability to each particular clinical laboratory.

Fundamentally, compliance efforts are designed to establish a culture within a clinical laboratory that promotes prevention, detection and resolution of instances of conduct that do not conform to federal and state law, and federal, state and private payor health care program requirements, as well as the clinical laboratory's ethical and business policies. In practice, the compliance program should effectively articulate and demonstrate the organization's commitment to the compliance process. The existence of benchmarks that demonstrate implementation and achievements are essential to any effective compliance program. Eventually, a

¹This guidance is a republication of the model clinical laboratory compliance plan issued by the OIG on February 27, 1997. This guidance has been amended to reflect HCFA policy changes and to be consistent with the OIG's Compliance Program Guidance for Hospitals. See 63 Fed. Reg. 8987 (Feb. 23, 1998); OIG's website at <http://www.dhhs.gov/progorg/oig>.

compliance program should become part of the fabric of routine clinical laboratory operations.

Specifically, compliance programs guide a clinical laboratory's governing body (e.g., Board of Directors), Chief Executive Officer (CEO), managers, technicians, billing personnel, and other employees in the efficient management and operation of a clinical laboratory. These employees are especially critical as an internal control in the reimbursement and payment areas, where claims and billing operations are often the source of fraud and abuse and, therefore, historically have been the focus of Government regulation, scrutiny and sanctions.

It is incumbent upon a clinical laboratory's corporate officers and managers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate ethical and legal conduct. Indeed, many clinical laboratories and clinical laboratory organizations have adopted mission statements articulating their commitment to high ethical standards. A formal compliance program, as an additional element in this process, offers a clinical laboratory a further concrete method that may improve quality of services and reduce waste. Compliance programs also provide a central coordinating mechanism for furnishing and disseminating information and guidance on applicable statutes, regulations and other requirements of federal, state and private health plans.

Adopting and implementing an effective compliance program requires a substantial commitment of time, energy and resources by senior management and the clinical laboratory's governing body.² Programs hastily constructed and implemented without appropriate ongoing monitoring will likely be ineffective. While it may require significant additional resources or reallocation of existing resources to implement an effective compliance program, the OIG believes that the long term benefits of implementing the program outweigh the costs.

²Indeed, recent case law suggests that the failure of a corporate Director to attempt in good faith to institute a compliance program in certain situations may be a breach of a Director's fiduciary obligation. See, e.g., In re Caremark International Inc. Derivative Litigation, 698 A.2d 959 (Ct. Chanc. Del. 1996).

A. BENEFITS OF A COMPLIANCE PROGRAM

In addition to fulfilling its legal duty to ensure that it is not submitting false or incorrect claims to Government and private payors, a clinical laboratory may gain numerous additional benefits by implementing an effective compliance program. Such programs make good business sense in that they help a clinical laboratory fulfill its fundamental mission of providing quality services as well as assisting clinical laboratories in identifying weaknesses in internal systems and management. Other important potential benefits include the ability to:

- concretely demonstrate to employees and the community at large the clinical laboratory's strong commitment to honest and responsible corporate conduct;
- provide a more accurate view of employee behavior relating to fraud and abuse;
- identify and prevent criminal and unethical conduct;
- improve the quality, efficiency and consistency of services;
- create a centralized source for distributing information on health care statutes, regulations and other program directives related to fraud and abuse and related issues;
- develop a methodology that encourages employees to report potential problems;
- develop procedures that allow the prompt, thorough investigation of alleged misconduct by corporate officers, managers and other employees;
- initiate immediate, appropriate, and decisive corrective action; and
- through early detection and reporting, minimize the loss to the Government from false claims, and thereby reduce the clinical laboratory's exposure to

civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion.³

Overall, the OIG believes that an effective compliance program is a sound investment on the part of a clinical laboratory.

The OIG recognizes that the implementation of a compliance program may not entirely eliminate fraud, abuse and waste from the clinical laboratory system. However, a sincere effort by clinical laboratories to comply with applicable federal and state standards, as well as the requirements of private health care programs, through the establishment of an effective compliance program, significantly reduces the risk of unlawful or improper conduct.

B. APPLICATION OF COMPLIANCE PROGRAM GUIDANCE

There is no single “best” clinical laboratory compliance program, given the diversity of laboratories within the industry. The OIG understands the variances and complexities within the clinical laboratory industry and is sensitive to the differences among large and small clinical laboratories. However, elements of this guidance can be used by all clinical laboratories, regardless of size, location or corporate structure, to establish an effective compliance program. We recognize that some clinical laboratories may not be able to adopt certain elements to the same comprehensive degree that others with more extensive resources may achieve. This guidance represents the OIG’s suggestions on how a clinical laboratory can best establish internal controls and monitoring to correct and prevent fraudulent activities. By no means should the contents of this guidance be viewed as an exclusive discussion of the advisable elements of a compliance program.

³The OIG, for example, will consider the existence of an effective compliance program that pre-dated any Governmental investigation when addressing the appropriateness of administrative penalties. Further, the False Claims Act, 31 U.S.C. §§ 3729-3733, provides that a person who has violated the Act, but who voluntarily discloses the violation to the Government, in certain circumstances will be subject to not less than double, as opposed to treble, damages. See 31 U.S.C. § 3729(a).

In drafting this guidance, we took into consideration the Model Compliance Plan for Clinical Laboratories issued by the OIG in February 1997, the clinical laboratory industry's comments on that plan, changes in HCFA policy and the OIG's Compliance Program Guidance for Hospitals.

As appropriate, this guidance may be further modified and expanded as more information and knowledge is obtained by the OIG, and as changes in the rules, policies and procedures of the federal, state and private health plans occur. We recognize that clinical laboratories are already accountable for complying with an extensive set of statutory and other legal requirements, far more specific and complex than what we have referenced in this document. We also recognize that the development and implementation of compliance programs in clinical laboratories often raise sensitive and complex legal and managerial issues.⁴ However, the OIG wishes to offer what it believes is critical guidance for providers who are sincerely attempting to comply with the relevant health care statutes, regulations and other requirements of federal, state and private health plans.

II. COMPLIANCE PROGRAM ELEMENTS

The elements proposed by these guidelines are similar to those of the compliance program guidance for hospitals that was published by the OIG in February 1998 and of our corporate integrity agreements.⁵ The elements represent a guide — a process that can be used by clinical laboratories, whether an independent national laboratory, a hospital laboratory, or a small, regional laboratory. Moreover, the elements can be incorporated into the managerial structure of the clinical laboratory. As we stated in our compliance program guidance for hospitals, these suggested guidelines can be tailored to fit the needs and financial realities of a particular laboratory. The OIG is cognizant that with regard to compliance programs, one

⁴Nothing stated herein should be substituted for, or used in lieu of, competent legal advice from counsel.

⁵Corporate integrity agreements are executed as part of a civil settlement agreement between the health care provider and the Government to resolve a case based on allegations of health care fraud or abuse. These OIG-imposed programs are in effect for a period of three to five years and require many of the elements included in this compliance program guidance.

model is not suitable to every clinical laboratory. Nonetheless, the OIG believes that every clinical laboratory, regardless of size or structure, can benefit from the principles espoused in this guidance.

The OIG believes that every effective compliance program must begin with a formal commitment by the clinical laboratory's governing body to include all of the applicable elements listed below. These elements are based on the seven steps of the Federal Sentencing Guidelines.⁶ We recognize that full implementation of all elements may not be immediately feasible for all clinical laboratories. However, as a first step, a good faith and meaningful commitment on the part of the clinical laboratory will substantially contribute to a program's successful implementation.

At a minimum, comprehensive compliance programs should include the following seven elements:

- (1) the development and distribution of written standards of conduct, as well as written policies and procedures that promote the clinical laboratory's commitment to compliance (e.g., by including adherence to compliance as an element in evaluating managers and employees) and that address specific areas of potential fraud, such as marketing schemes, CPT/HCPCs coding issues, improper ICD-9 coding, and improper claims submission;
- (2) the designation of a chief compliance officer and other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body;
- (3) the development and implementation of regular, effective education and training programs for all affected employees;
- (4) the maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

⁶See United States Sentencing Commission Guidelines, Guidelines Manual, 8A1.2 comment. (n.3(k)).

- (5) the development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or requirements of federal, state or private health plans;
- (6) the use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
- (7) the investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

A. WRITTEN PROCEDURES AND POLICIES

Laboratory compliance programs should require the development and distribution of written compliance policies. These policies should be developed under the supervision and direction of the chief compliance officer or the equivalent and should, at a minimum, be provided to all individuals who are affected by the specific policy at issue. One convenient method of achieving this goal is to create a three-ring compliance policy notebook. This format permits the filing of new and amended or revised compliance policies and ensures that affected individuals have easy access to the laboratory's written policies. A master index should show when policies are changed.

1. Standards of Conduct

Laboratories should develop standards of conduct for all employees that clearly delineate the policies of the laboratory with regard to fraud, waste and abuse and adherence to all statutes, regulations and other program requirements governing federal, state and private health benefit plans. These standards should be made available to all employees; translated, interpreted (e.g., may be signed for hard of hearing or deaf employees) or put into Braille as necessary, and regularly updated as the policies and regulations are modified.

When an employee first begins working for the clinical laboratory, and each time new standards of conduct are issued, employees should be asked to sign a statement

certifying that they have received, read, and understood the standards of conduct. All employee certifications should be retained by the laboratory.

2. Medical Necessity

Laboratory compliance programs, to be effective, should communicate to physicians that claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary, given his or her clinical condition. Laboratories should take all reasonable steps to ensure that it is not submitting claims for services that are not covered, reasonable and necessary.⁷ Upon request, a laboratory should be able to produce or obtain from the treating physician (test ordering), authorized person on the physician's staff or other individual authorized by law to order tests the documentation to support the medical necessity of the service the laboratory has provided and billed to a federal or private health care program. We recognize that laboratories do not and cannot treat patients or make medical necessity determinations. However, there are steps that such facilities can take to assure compliance with the applicable statutes, regulations and the requirements of federal, state and private health plans.

As a preliminary matter, the OIG recognizes that physicians or other authorized individuals must be able to order any tests that they believe are appropriate for the treatment of their patients. However, we believe that physicians must be made aware by the billing laboratory that Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose an individual patient. Section 1862(a)(1)(A) of the Social Security Act states, "no payment may be made under Part A or Part B for any expenses incurred for items or services which...are not reasonable and necessary for the diagnosis or treatment of

⁷In limited instances, HCFA does allow laboratories to submit claims when the lab believes the test may be denied. Such instances include, but are not limited to: when the beneficiary has signed an Advance Beneficiary Notice (ABN) (See Medicare Carriers Manual §7300.5) (Part D in this section further addresses ABN issues) and when the beneficiary requests the provider submit the claim (See Medicare Carriers Manual §3043). In the first instance the lab should include modifier GA on the claim which indicates the beneficiary has signed an ABN and in the latter instance the lab should note on the claim their belief that the service is noncovered and that it is being submitted at the beneficiary's insistence.

an illness or injury or to improve the functioning of a malformed body member.” Therefore, Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record, including that maintained in the physician’s records, does not support that the tests were reasonable and necessary for a given patient. Laboratories can and should advise their clients that tests submitted for Medicare reimbursement must meet program requirements⁸ or the claim may be denied.

Laboratories may implement the following steps through their compliance programs or some other appropriate mechanism to ensure that the claims they submit to federal or private health care programs meet the appropriate program requirements:

a. Requisition Design: While HCFA does not design or approve requisition forms, laboratories should construct the requisition form to capture the correct program information as required by federal or private health care programs and to promote the conscious ordering of tests by physicians or other authorized individuals. The laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill. Laboratories should encourage physicians or other authorized individuals to submit diagnosis information for all tests ordered, as documentation of the medical necessity of the service. The form should contain a statement indicating that Medicare generally does not cover routine screening tests.

b. Notices to Physicians: While HCFA does not impose educational requirements upon the laboratories, labs are in a unique position to educate their physician clients. Therefore, laboratories should provide all of their physician clients with annual written notices that set forth: (1) the Medicare national policy and Medicare contractor local medical review policy for lab tests; (2) that organ or disease related panels will only be paid and will only be billed when all components are medically necessary; and (3) the Medicare laboratory fee schedule and a statement informing the physician that the Medicaid reimbursement amount will be equal to or less than the amount of Medicare reimbursement. The notice must also provide the phone number of the clinical consultant. The clinical consultant is

⁸See fn. 7.

required under the Clinical Laboratory Improvement Amendment (CLIA) certification (42 CFR §493.1453).

In addition to the general notices above, laboratories that continue to offer clients the opportunity to request customized profiles should provide annual written notices that: (1) explain the Medicare reimbursement paid for each component of each such profile; (2) inform physicians that using a customized profile may result in the ordering of tests which are not covered, reasonable or necessary and that tests will not be billed;⁹ and (3) inform physicians that the OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.

c. Physician Acknowledgments: Although HCFA does not require physicians to sign acknowledgments, laboratories should have the physician sign an acknowledgment stating he or she understands the potential implications of ordering customized profiles.

d. Use of Advance Beneficiary Notices (ABNs): Advance Beneficiary Notices are used when there is a likelihood that an ordered service will not be paid. Before the service is furnished, the beneficiary should be notified, in writing, of the likelihood that the specific service will be denied. After being so informed the beneficiary has the choice to either (1) decide to receive the service and sign the agreement to pay on the ABN or (2) decide not to receive the service and therefore does not sign the ABN. Beneficiaries should not be asked to sign blank ABNs.

As the entity furnishing and billing for services, it is ultimately the laboratory's responsibility to produce the ABN, upon request. In many cases, it is difficult for the laboratories to directly obtain an ABN from the beneficiary. Therefore, laboratories may wish to educate physicians on the appropriate use of ABNs.

The notice must be in writing, must clearly identify a particular service, must state that payment for the particular service likely will be denied and must give the reason(s) for the belief that payment is likely to be denied.

⁹See fn. 7.

Routine notices to beneficiaries which do no more than state that denial of payment is possible or that they never know whether payment will be denied are not considered acceptable evidence of advance notice. Notices should not be given to beneficiaries unless there is some genuine doubt regarding the likelihood of payment as evidenced by the reasons stated on the ABN. Giving notice for all claims or services is not an acceptable practice.

e. Test Utilization Monitoring: The OIG believes that laboratories can and should take the steps described in this compliance guidance to help ensure appropriate billing of lab tests. We also believe that there are steps laboratories can take to determine whether physicians or other individuals authorized to order tests are being encouraged to order medically unnecessary tests. More importantly, if the laboratory discovers that it has in some way contributed to the ordering of unnecessary tests, the OIG believes the laboratory has a duty to modify its practices, as well as notify the physician(s) or other authorized individual(s) of its concerns and recommend corrective action.

There are many methods by which a laboratory may determine excessive utilization of laboratory services. One approach to self-monitoring is to hire an outside consultant to analyze the laboratory's patterns of utilization, and investigate any potential problems or aberrancies.

Another approach is to analyze test utilization data by CPT or HCPCS code, for the top 30 tests performed each year. Laboratories could do this by keeping track of the number of tests performed by CPT or HCPCS code or of the number of claims submitted for each test. The laboratories would then compute the percentage growth in the number of tests or claims submitted for each of the top 30 tests from one year to the next. We believe that if a test's utilization grows more than 10 percent, the laboratory should undertake a reasonable inquiry to ascertain the cause of such growth. If the laboratory determines that the increase in test utilization occurred for a benign reason, such as the acquisition of a new laboratory facility, then the laboratory need not take any action. However, if the laboratory determines that the increase in utilization was caused by a misunderstanding or ignorance by the ordering physicians or other authorized individuals regarding the billing consequences of the tests they ordered or an action on the part of the facility, the laboratory should take any steps that it deems reasonably necessary to address the issue and to ensure misconduct is not occurring.

3. Billing

Laboratory compliance policies should ensure that all claims for testing services submitted to Medicare or other federal health care programs correctly identify the services ordered by the physician or other authorized individual and performed by the laboratory.

a. Selection of CPT or HCPCS Codes: Laboratory compliance policies should ensure that the CPT or HCPCS code that is used to bill, accurately describes the service that was ordered and performed. Laboratories cannot alter the physician's order in any way either increasing or decreasing the number of services performed without the express consent of the ordering physician or other authorized individual. To ensure code accuracy, laboratories should require that individuals with technical expertise in laboratory testing review the appropriateness of the codes before the claims are submitted. Intentional or knowing upcoding (*i.e.*, the selection of a code to maximize reimbursement when such code is not the most appropriate descriptor of the service) could violate the False Claims Act and/or other civil laws, and criminal law.

b. Selection of ICD-9-CM Codes: Medicare carriers and fiscal intermediaries have the authority to develop and implement Local Medical Review Policy (LMRP) which specify when, and under what circumstances, a service will be considered covered, reasonable and necessary and what documentation will support the need for the service. In some cases, LMRPs may limit coverage for specified laboratory tests to specific medical diagnoses. Laboratory compliance policies should ensure that the lab can support tests billed to Medicare with documentation obtained from the physician ordering the test, an authorized person on the physician's staff or other individual authorized by law to order tests. Laboratories should not: (1) use information provided by the physician or other authorized individual from earlier dates of service (other than standing orders, as discussed below at paragraph 4); (2) create diagnosis information that has triggered reimbursement in the past; (3) use computer programs that automatically insert diagnosis codes without receipt of diagnostic information from the ordering physician or other authorized individual; or (4) make up information for claim submission purposes. Laboratories should: (1) contact the ordering physician, authorized person on the physician's staff or other individual authorized to order tests to obtain information in the event that such information was not provided; and (2) accurately translate narrative diagnoses obtained from the physician or other

authorized individual to ICD-9-CM codes. Where medical documentation is obtained from a physician or other authorized individual after receipt of the specimen and the requisition form, it should be maintained.

c. Tests Covered by Claims for Reimbursement: Only those tests that are ordered by an authorized individual or physician, are performed and meet Medicare's conditions of coverage are reimbursable by Medicare. If a laboratory receives a specimen without a valid test order or with a test order which is ambiguous, the laboratory must verify the tests which the physician wants and perform them before submitting a claim for reimbursement to Medicare. In this way, if the physician or other authorized individual did not order the test, the laboratory will not erroneously bill for it.

Similarly, if a laboratory did not perform an ordered test due to, for example, a laboratory accident or insufficient quantities of specimen, the laboratory should not submit a claim to Medicare. Medicare payment is made for tests that are ordered, performed, and covered. The submission of a claim for tests that were either not ordered or were not performed could subject a provider to sanctions under administrative, civil or criminal law.

d. Billing of Calculations: Consistent with Medicare coverage rules, laboratory compliance policies should ensure that the laboratory does not bill both for calculations (e.g., calculated LDLs, T7s, and indices) and the tests that are performed to derive such calculations. In many situations, physicians are not offered a choice about whether to receive such calculations, nor are they aware of the practice of some laboratories to bill Medicare for such calculations in addition to the underlying tests. The fact that a separate CPT code exists does not mean that Medicare separately reimburses for the service assigned to the code. Billing both for the calculations and the underlying tests constitutes double billing, which may subject a laboratory to sanctions and other remedies available under civil, criminal, and administrative law.

e. Reflex Testing: Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate. In order to avoid performing unnecessary reflex tests, labs may want to design their requisition form in such a way which would only allow for the reflex test when necessary. Therefore, the condition under which the reflex test

will be performed should be clearly indicated on the requisition form. Labs may wish to adopt a similar policy for confirmation testing, which may be mandatory.

4. Reliance on Standing Orders

Although standing orders are not prohibited in connection with an extended course of treatment, too often they have led to abusive practices. Standing orders in and of themselves are not usually acceptable documentation that tests are reasonable and necessary. Accordingly, the insurer may reject standing orders as evidence that a test is reasonable and necessary. Medicare contractors can and may require additional documentation to support the medical necessity of the test. As a result of the potential problems standing orders may cause, the use of standing orders is discouraged.

Thus, while laboratory compliance programs may permit the use of standing orders executed in connection with an extended course of treatment, the compliance program should require the laboratory to periodically monitor standing orders. Standing orders should have a fixed term of validity and must be renewed at their expiration. We suggest that, consistent with state law requirements, a laboratory should contact all nursing homes from which the laboratory has received such standing orders and request that they confirm in writing the validity of all current standing orders. In addition, in accordance with state law, laboratories should verify standing orders relied upon at draw stations with the physician, authorized person on the physician's staff, or other authorized individual who has provided the standing orders to the laboratory. With respect to patients with End Stage Renal Disease (ESRD), at least once annually laboratories should contact each ESRD facility or unit to request confirmation in writing of the continued validity of all existing standing orders.

5. Compliance with Applicable HHS Fraud Alerts

The OIG and HCFA periodically issue fraud alerts¹⁰ setting forth activities believed to raise legal and enforcement issues. Laboratory compliance programs should

¹⁰Both OIG and HCFA fraud alerts can be located on the internet. The OIG website address is: <http://www.dhhs.gov/progorg/oig>. The HCFA website address is: <http://www.hcfa.gov>.

require that any and all fraud alerts issued by OIG and HCFA are carefully considered by the legal staff, chief compliance officer, or other appropriate personnel. Moreover, the compliance programs should require that a laboratory cease and correct any conduct criticized in such a fraud alert, if applicable to laboratories, and take reasonable action to prevent such conduct from reoccurring in the future. If appropriate, a laboratory should take the steps described in Section G regarding investigations, reporting and correction of identified problems.

6. Marketing

Laboratory compliance programs should require honest, straightforward, fully informative and non-deceptive marketing. It is in the best interests of patients, physicians, laboratories, the Government and private health plans that physicians and other individuals authorized to order tests fully understand the services offered by the laboratory, the services that will be provided when tests are ordered, and the financial consequences for Medicare, as well as other payors, when tests are billed. Accordingly, laboratories that market their services should ensure that their marketing information is clear, correct, non-deceptive and fully informative.

7. Prices Charged to Physicians

Laboratories are paid for their services by a variety of payors in addition to Medicare and other federal health care programs. Such payors often include private health insurers, other health care providers, and physicians. We believe it is essential that the physician take into account the patient's best interest when deciding where to refer the patient's specimen.

The prices that laboratories charge physicians for certain laboratory services raise issues that should be addressed in a laboratory's written compliance policies. These policies should ensure that laboratories are not providing any inducements to gain a physician's business,¹¹ including charging physicians a price below fair market value for their non-federal health care program tests. Laboratories that charge physicians

¹¹The OIG has published "Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services" that addresses how the anti-kickback statute relates to arrangements for the provision of clinical lab services. See 59 Fed. Reg. 65,377 (December 19, 1994); OIG's website at <http://www.dhhs.gov/progorg/oig>.

a price below fair market value to induce them to refer their federal health care program business may be risking anti-kickback enforcement and false claims actions.

8. Retention of Records

Compliance programs should ensure that all records required either by federal or state law or by the compliance program are created and maintained. Adequate documentation of compliance efforts are essential in the event that a laboratory comes under government scrutiny.

9. Compliance As An Element of a Performance Plan

Clinical laboratories should make the promotion of and adherence to compliance an element in evaluating the performance of managers, supervisors and all other employees. They, along with other employees, should be periodically trained in new compliance policies and procedures. In addition, all managers and supervisors involved in the sale, marketing, or billing of laboratory services, and those who oversee phlebotomists should: (1) discuss with all supervised employees the compliance policies and legal requirements applicable to their function; (2) inform all supervised personnel that strict compliance with these policies and requirements is a condition of employment; and (3) disclose to all supervised personnel that the laboratory will take disciplinary action up to and including termination for violation of these policies or requirements. In addition to making performance of these duties an element in evaluations, the compliance officer or laboratory management may also choose to include in the laboratory's compliance program a policy that managers and supervisors may be sanctioned for failure to adequately instruct their subordinates or for failing to detect non-compliance with applicable policies and legal requirements, where reasonable diligence on the part of the manager or supervisor would have led to the discovery of any problems or violations and given the laboratory the opportunity to correct them earlier.

B. DESIGNATION OF A COMPLIANCE OFFICER AND A COMPLIANCE COMMITTEE

1. Compliance Officer

Every clinical laboratory should designate a compliance officer to serve as the focal point for compliance activities. This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the clinical laboratory and the complexity of the task. Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official in the organization with direct access to the governing body and the CEO.¹² The officer should have sufficient funding and staff to perform his or her responsibilities fully. Coordination and communication are the key functions of the compliance officer with regard to planning, implementing, and monitoring the compliance program.

The compliance officer's primary responsibilities should include:

- overseeing and monitoring the implementation of the compliance program;¹³

¹²The OIG believes that it is not advisable for the compliance function to be subordinate to the clinical laboratory's general counsel, or comptroller or similar officer. Free standing compliance functions help to ensure independent and objective legal reviews and financial analyses of the institution's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the clinical laboratory make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

¹³For clinical laboratory chains, the OIG encourages coordination with each affiliate owned by the company through the use of a headquarter's compliance officer, communicating with the designated compliance officers in each facility, or regional office, as appropriate.

- reporting on a regular basis to the clinical laboratory's governing body, CEO and compliance committee on the progress of implementation, and assisting these components in establishing methods to improve the clinical laboratory's efficiency and quality of services, and to reduce the clinical laboratory's vulnerability to fraud, abuse and waste;
- developing and distributing to all affected employees all written compliance policies and procedures. These policies and procedures should be readily understandable by all employees (e.g., translated into other languages, interpreted in sign language, and/or put into Braille as necessary);
- periodically revising the program in light of changes in the needs of the organization, and in the law, policies and procedures of Government and private payor health plans;
- developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeks to ensure that all appropriate employees and management are knowledgeable of, and comply with, pertinent federal, state and private payor standards;
- ensuring that physicians who order services from the clinical laboratory are informed of the clinical laboratory's compliance program standards with respect to coding, billing, and marketing, among other things;
- assisting the clinical laboratory's financial management in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of policies;
- independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action; and
- developing policies and programs that encourage managers and employees to report suspected fraud and other improprieties without fear of retaliation.

The compliance officer must have the authority to review all documents and other information that are relevant to compliance activities, including, but not limited to, requisition forms, billing information, claim information, and records concerning the marketing efforts of the clinical laboratory and its arrangements with its clients. This policy enables the compliance officer to review contracts and obligations (seeking the advice of legal counsel, where appropriate) that may contain referral and payment issues that could violate the anti-kickback statute, as well as the physician self-referral prohibition and other legal or regulatory requirements.

2. Compliance Committee

The OIG recommends that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.¹⁴ The committee's functions should include:

- analyzing the organization's regulatory environment, the legal requirements with which it must comply, and specific risk areas;
- assessing existing policies and procedures that address these areas for possible incorporation into the compliance program;
- working within the clinical laboratory to develop standards of conduct and policies and procedures to promote compliance;
- recommending and monitoring the development of internal systems and controls to implement the clinical laboratory's standards, policies and procedures as part of its daily operations;
- determining the appropriate strategy/approach to promote compliance with the program and detection of any potential violations, such as through hotlines and other fraud reporting mechanisms; and
- developing a system to solicit, evaluate and respond to complaints

¹⁴The OIG recommends the compliance committee consist of individuals with varying perspectives and responsibilities in the organization.

and problems.

The committee may also assume other functions as the compliance concept becomes part of the overall clinical laboratory operating structure and daily routine.

C. CONDUCTING EFFECTIVE TRAINING AND EDUCATION

The proper education, training and retraining of corporate officers, managers, and all other employees are significant elements of an effective compliance program. As part of its compliance program, a clinical laboratory should require all affected employees to attend specific training when they are first hired and on a periodic basis thereafter, including appropriate training in federal and state statutes, regulations, program requirements, the policies of private payors, and corporate ethics. The training should emphasize the organization's commitment to compliance with these legal requirements and policies.

These training programs should include sessions highlighting the organization's compliance program, summarizing fraud and abuse laws, and discussing coding requirements, claim development, claim submission process, and marketing practices that reflect current legal and program standards. The clinical laboratory must take steps to communicate effectively its standards and procedures to all affected employees (e.g., by requiring participation in training programs and disseminating publications that explain in a practical manner specific requirements).¹⁵ Managers of specific departments can assist in identifying areas that require training and in carrying out such training. Training instructors may come from outside or inside the organization. New employees should be targeted for training early in their employment.¹⁶ The compliance officer should document

¹⁵Some publications, such as the OIG's Special Fraud Alerts, audit and inspection reports, and advisory opinions are readily available from the OIG and could be the basis for standards and educational courses for appropriate clinical laboratory employees. These documents can be found on the OIG's website at <http://www.dhhs.gov/progorg/oig>.

¹⁶Certain positions, such as those involving the coding of medical services, create a greater organizational legal exposure, and therefore require specialized training. One recommendation would be for a clinical laboratory to attempt to fill
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the attendees, the subjects covered, and the material distributed at the training sessions sponsored by the clinical laboratory as part of the compliance program.

A variety of teaching methods, such as interactive training, and training in several different languages, particularly where a clinical laboratory has a culturally diverse staff, should be implemented so that all affected employees are knowledgeable of the clinical laboratory's standards of conduct and procedures for alerting senior management to problems and concerns. Targeted training should be provided to corporate officers, managers and other employees whose actions affect the accuracy of the claims submitted to Government and private payors, such as employees involved in the coding, billing, and marketing processes. For example, for certain employees involved in the billing and coding functions, periodic training in proper CPT/HCPCs and ICD-9 coding and documentation should be required. In addition to specific training in the areas identified in section II.A, above, basic training for appropriate corporate officers, managers and other employees should include such topics as:

- Government and private payor reimbursement principles;
- general prohibitions on paying or receiving remuneration to induce referrals;
- proper translation of narrative diagnoses;
- only billing for services ordered, performed, and reported;
- physician approved amendments to requisition forms;
- proper documentation or confirmation of services rendered; and
- duty to report misconduct.

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such positions with individuals who have the appropriate educational background and training.

Clarifying and emphasizing these areas of concern through training and educational programs are particularly relevant to the clinical laboratory's marketing representatives, in that the pressure to meet business goals may render these employees vulnerable to engaging in prohibited practices.

The OIG suggests that all affected employees be made part of the clinical laboratory's various educational and training programs. Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities.¹⁷ In departments with high employee turnover, periodic training updates are critical.

The OIG recommends that attendance and participation in training programs be made a condition of continued employment and that failure to comply with training requirements should result in disciplinary action, including possible termination, when such failure is serious. Adherence to the provisions of the compliance program, such as training requirements, should be a factor in the annual evaluation of each employee. The clinical laboratory should retain adequate records of its training of employees, including attendance logs and material distributed at training sessions.

D. DEVELOPING EFFECTIVE LINES OF COMMUNICATION

1. Access to the Compliance Officer

An open line of communication between the compliance officer and clinical laboratory employees is equally important to the successful implementation of a compliance program and the reduction of any potential for fraud, abuse and waste. Written confidentiality and non-retaliation policies should be developed and distributed to all employees to encourage communication and the reporting of incidents of potential misconduct.¹⁸ The compliance committee should also develop

¹⁷ In its corporate integrity agreements, the OIG usually requires a minimum number of hours annually for basic training in compliance areas. More hours are required for specialty fields such as billing and coding.

¹⁸ The OIG believes that whistleblowers should be protected against retaliation, a concept embodied in the provisions of the False Claims Act. In many
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several independent reporting paths for an employee to report fraud, waste or abuse so that such reports cannot be diverted by supervisors or other personnel.

The OIG encourages the establishment of a procedure so that clinical laboratory employees may seek clarification from the compliance officer or members of the compliance committee in the event of any confusion or question with regard to a laboratory policy or procedure. Questions and responses should be documented and dated and, if appropriate, shared with other staff so that standards, policies and procedures can be updated and improved to reflect any necessary changes or clarifications. The compliance officer may want to solicit employee input in developing these communication and reporting systems.

2. Hotlines and Other Forms of Communication

The OIG encourages the use of hotlines (including anonymous hotlines), e-mails, written memoranda, newsletters, and other forms of information exchange to maintain these open lines of communication. If the clinical laboratory establishes a hotline, the telephone number should be made readily available to all employees possibly by conspicuously posting the telephone number in common work areas.¹⁹ Employees should be permitted to report matters on an anonymous basis. Matters reported through the hotline or other communication sources that suggest substantial violations of compliance policies, regulations, statutes or program requirements of federal, state and private insurers should be documented and investigated promptly to determine their veracity. A log should be maintained by the compliance officer that records such calls, including the nature of any investigation and its results. Such information should be included in reports to the governing body, the CEO and compliance committee. Further, while the clinical laboratory should always strive to maintain the confidentiality of an employee's identity, it should also explicitly

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cases, employees sue their employers under the False Claims Act's qui tam provisions out of frustration because of the company's failure to take action when a questionable, fraudulent or abusive situation was brought to the attention of senior corporate officials.

¹⁹Clinical laboratories should also post in a prominent, available area the HHS-OIG Hotline telephone number, 1-800-HHS-TIPS (447-8477), in addition to any company hotline number that may be posted.

communicate that there may be a point where the individual's identity may become known or may have to be revealed in certain instances when Governmental authorities become involved.

The OIG recognizes that assertions of fraud and abuse by employees who may have participated in illegal conduct or committed other malfeasance raise numerous complex legal and management issues that should be examined on a case-by-case basis. The compliance officer should work closely with legal counsel, who can provide guidance regarding such issues.

E. ENFORCING STANDARDS THROUGH WELL-PUBLICIZED DISCIPLINARY GUIDELINES

1. Discipline Policy and Actions

An effective compliance program should include guidance regarding disciplinary action for corporate officers, managers, and other employees who have failed to comply with the clinical laboratory's standards of conduct, policies and procedures, or federal and state laws, or those who have otherwise engaged in wrongdoing, which have the potential to impair the clinical laboratory's status as a reliable, honest and trustworthy health care provider.

The OIG believes that the compliance program should include a written policy statement setting forth the degrees of disciplinary actions that may be imposed upon corporate officers, managers, and other employees for failing to comply with the clinical laboratory's standards and policies and applicable statutes and regulations. Intentional or reckless noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension or termination. The written standards of conduct should elaborate on the procedures for handling disciplinary problems and those who will be responsible for taking appropriate action. Some disciplinary actions can be handled by department managers, while others may have to be resolved by a senior manager. Disciplinary action may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct. Employees should be advised by the clinical laboratory that disciplinary action will be taken on a fair and equitable basis. Managers and supervisors should be made aware that they have a responsibility to discipline employees in an appropriate and consistent manner.

It is vital to publish and disseminate the range of disciplinary standards for improper conduct and to educate corporate officers, managers and other employees regarding these standards. The consequences of noncompliance should be consistently applied and enforced, in order for the disciplinary policy to have the required deterrent effect. All levels of employees should be subject to the same disciplinary action for the commission of similar offenses. The commitment to compliance applies to all personnel levels within a clinical laboratory. The OIG believes that corporate officers, managers, and other employees should be held accountable for failing to comply with, or for the foreseeable failure of their subordinates to adhere to, the applicable standards, laws, and procedures.

2. New Employee Policy

For all new employees who have discretionary authority to make decisions that may involve compliance with the law or compliance oversight, clinical laboratories should conduct a reasonable and prudent background investigation, including a reference check, as part of every such employment application.²⁰ The application should specifically require the applicant to disclose any criminal conviction, as defined by 42 U.S.C. § 1320a-7(i), or exclusion action. Pursuant to the compliance program, clinical laboratory policies should prohibit the employment of individuals who have been recently convicted of a criminal offense related to health care or who are listed as debarred, excluded or otherwise ineligible for participation in federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)).²¹ In addition,

²⁰The Cumulative Sanction Report is an OIG-produced report available on the Internet at <http://www.dhhs.gov/progorg/oig>. It is updated on a regular basis to reflect the status of health care providers who have been excluded from participation in the Medicare and Medicaid programs. In addition, the General Services Administration maintains a monthly listing of debarred contractors on the Internet at <http://www.arnet.gov/epl>. Also, once the data base established by the Health Care Fraud and Abuse Data Collection Act of 1996 is fully operational, the hospital should regularly request information from this data bank as part of its employee screening process.

²¹Likewise, clinical laboratory compliance programs should establish standards prohibiting the execution of contracts with physicians or other individuals authorized to order tests that have been recently convicted of a criminal offense
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pending the resolution of any criminal charges or proposed debarment or exclusion, the OIG recommends that such individuals should be removed from direct responsibility for or involvement in any federal health care program.²² With regard to current employees, physicians or other individuals authorized to order tests, physicians, if resolution of the matter results in conviction, debarment or exclusion, the clinical laboratory should terminate its employment or other contract arrangement with the individual or physician.

F. AUDITING AND MONITORING

An ongoing evaluation process involving thorough monitoring and regular reporting to the clinical laboratory's corporate officers is critical to a successful compliance program. Compliance reports created by this ongoing monitoring, including reports of suspected noncompliance, should be maintained by the compliance officer and shared with the clinical laboratory's corporate officers and the compliance committee.

Although many monitoring techniques are available, one effective tool to promote and ensure compliance is the performance of regular compliance audits by internal or external auditors who have expertise in federal and state health care statutes, regulations and the program requirements of federal, state and private insurers. At a minimum, these audits should be designed to address the clinical laboratory's compliance with laws governing kickback arrangements, the physician self-referral prohibition, CPT/HCPCS coding and billing, ICD-9 coding, claim development and submission, reimbursement, marketing, reporting and record keeping. In addition, the audits and reviews should inquire into the clinical laboratory's compliance with specific rules and policies that have been the focus of particular attention on the part of the Medicare fiscal intermediaries or carriers, and law enforcement, as evidenced by OIG Special Fraud Alerts, OIG audits and evaluations, and publically announced law enforcement initiatives and also should focus on any areas of concern that have

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related to health care or that are listed by a federal agency as debarred, excluded, or otherwise ineligible for participation in federal health care programs.

²²Prospective employees who have been officially reinstated into the Medicare and Medicaid programs by the OIG may be considered for employment upon proof of such reinstatement.

been identified by any entity, (i.e., federal, state, or internally), specific to the individual clinical laboratory.

Monitoring techniques may include sampling protocols that permit the compliance officer to identify and review variations from an established baseline.²³ Significant variations from the baseline should trigger a reasonable inquiry to determine the cause of the deviation. If the inquiry determines that the deviation occurred for legitimate, explainable reasons, the compliance officer, corporate officer or manager may want to limit any corrective action or take no action. If it is determined that the deviation was caused by improper procedures, misunderstanding of rules, including fraud and systemic problems, the clinical laboratory should take prompt steps to correct the problem. If potential fraud or violations of the False Claims Act are involved, the laboratory should report the potential violation to the Office of Inspector General or the Department of Justice (see discussion in Section G.2, below). Any repayment of an overpayment which results from such a violation should be made as part of the discussion with law enforcement.

When making any overpayment, the clinical laboratory should inform the payor of the following information: (1) the refund is being made pursuant to a voluntary compliance program; (2) a description of the complete circumstances surrounding the overpayment; (3) the methodology by which the overpayment was determined; (4) any claim-specific information used to determine the overpayment and; (5) the amount of the overpayment.

²³The OIG recommends that when a compliance program is established in a clinical laboratory, the compliance officer, with the assistance of corporate officers, should take a “snapshot” of their operations from a compliance perspective. This assessment can be undertaken by outside consultants, law or accounting firms, or internal staff, with authoritative knowledge of health care compliance requirements. This “snapshot,” often used as part of benchmarking analyses, becomes a baseline for the compliance officer and other corporate officers to judge the clinical laboratory’s progress in reducing or eliminating potential areas of vulnerability. For example, it has been suggested that a baseline level include the frequency and percentile levels of each CPT code in relation to the clinical laboratory’s overall billing.

The OIG believes that the compliance officer needs to be made aware of these overpayment patterns, violations or deviations and look for trends that may demonstrate a systemic problem.

An effective compliance program should also incorporate periodic (at least annual) reviews of whether the program's compliance elements have been satisfied, e.g., whether there has been appropriate; (1) dissemination of the program's standards; (2) training; (3) ongoing educational programs; and (4) disciplinary actions, among others. This process will verify actual conformance with the compliance program. The review also should look into whether appropriate records have been created and maintained to document the implementation of an effective program. However, when monitoring discloses that deviations were not detected in a timely manner due to program deficiencies, appropriate modifications must be implemented. Such evaluations, when developed with the support of management, can help ensure compliance with the clinical laboratory's policies and procedures.

As part of the review process, the compliance officer or reviewers should consider techniques such as:

- on-site visits;
- interviews with personnel involved in management, marketing/sales, operations, coding/billing, claim development and submission, and other related activities;
- questionnaires developed to solicit impressions of a broad cross-section of the clinical laboratory's employees and clients;
- review of requisition forms and other documents that support claims for reimbursement;
- review of written materials and documentation produced by the laboratory and used by physicians and other individuals authorized to order test; and
- trend analyses, or longitudinal studies, that seek deviations in billing or ordering patterns over a given period.

The reviewers should:

- be independent of line management;
- have access to existing audit resources, relevant personnel and all relevant areas of operation;
- present written evaluative reports on compliance activities to the CEO, governing body and members of the compliance committee on a regular basis, but no less than annually; and
- specifically identify areas where corrective actions are needed.

With these reports, the clinical laboratory management can take whatever steps are necessary to correct past problems and prevent them from recurring. In certain cases, subsequent reviews or studies would be advisable to ensure that the recommended corrective actions have been implemented successfully.

The clinical laboratory should document its efforts to comply with applicable statutes, regulations and the program requirements of federal, state and private payors. For example, where a clinical laboratory, in its efforts to comply with a particular statute, regulation or program requirement, requests advice from a Government agency (including a Medicare fiscal intermediary or carrier) charged with administering a federal health care program, the clinical laboratory should document and retain a record of the request and any written or oral response. This step is particularly important if the clinical laboratory intends to rely on that response. The laboratory should memorialize its determination as to whether reliance on any such advice is reasonable, and its efforts to develop procedures based upon such advice.

G. RESPONDING TO DETECTED OFFENSES AND DEVELOPING CORRECTIVE ACTION INITIATIVES

1. Violations and Investigations

Violations of a clinical laboratory's compliance program, failures to comply with applicable federal or state law, and other requirements of Government and private health plans, and other types of misconduct threaten a clinical laboratory's status as

a reliable, honest and trustworthy provider capable of participating in federal health care programs. Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the clinical laboratory. Consequently, upon reports or reasonable indications of suspected noncompliance, it is important that the chief compliance officer or other management officials initiate prompt steps to investigate the conduct in question to determine whether a material violation of applicable law or the requirements of the compliance program has occurred, and if so, take steps to correct the problem.²⁴ As appropriate, such steps may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan,²⁵ a report to the Government,²⁶ and the submission of any overpayments, if applicable.

Depending upon the nature of the alleged violations, an internal investigation will probably include interviews and a review of relevant documents. Some clinical laboratories should consider engaging outside counsel, auditors, or health care

²⁴Instances of non-compliance must be determined on a case-by-case basis. The existence, or amount, of a monetary loss to a health care program is not solely determinative of whether or not the conduct should be investigated and reported to Governmental authorities. In fact, there may be instances where there is no monetary loss at all, but corrective action and reporting are still necessary to protect the integrity of the applicable program and its beneficiaries.

²⁵Advice from the clinical laboratory's in-house counsel or an outside law firm may be sought to determine the extent of the clinical laboratory's liability and to plan the appropriate course of action.

²⁶The OIG currently maintains a voluntary disclosure program that encourages providers to report suspected fraud. The concept of voluntary self-disclosure is premised on a recognition that the Government alone cannot protect the integrity of the Medicare and other federal health care programs. Health care providers must be willing to police themselves, correct underlying problems and work with the Government to resolve these matters. The OIG's voluntary self-disclosure program has four prerequisites: (1) the disclosure must be on behalf of an entity and not an individual; (2) the disclosure must be truly voluntary (*i.e.*, no pending proceeding or investigation); (3) the entity must disclose the nature of the wrongdoing and the harm to the federal programs; and (4) the entity must not be the subject of a bankruptcy proceeding before or after the self-disclosure.

experts to assist in an investigation. Records of the investigation should contain documentation of the alleged violation, a description of the investigative process, copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, the results of the investigation (e.g., any disciplinary action taken), and the corrective action implemented. While any action taken as the result of an investigation will necessarily vary depending upon the clinical laboratory and the situation, clinical laboratories should strive for some consistency by utilizing sound practices and disciplinary protocols. Further, after a reasonable period, the compliance officer should review the circumstances that formed the basis for the investigation to determine whether similar problems have since been uncovered.

If an investigation of an alleged violation is undertaken and the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, those subjects should be removed from their current work activity until the investigation is completed (unless otherwise requested by law enforcement). In addition, the compliance officer should take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation. If the clinical laboratory determines that disciplinary action is warranted, it should be prompt and imposed in accordance with the clinical laboratory's written standards of disciplinary action.

2. Reporting

If the compliance officer, compliance committee or management official discovers credible evidence of misconduct from any source and, after a reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil or administrative law, then the clinical laboratory promptly should report the matter to the appropriate Governmental authority²⁷ within a reasonable period, but not more than sixty (60) days²⁸ after determining that there is credible evidence of a

²⁷I.e., Federal and/or state law enforcement having jurisdiction over such matter. Such Governmental authority would include DOJ and OIG with respect to Medicare and Medicaid violations giving rise to causes of actions under various criminal, civil and administrative false claims statutes.

²⁸To qualify for the "not less than double damages" provision of the False Claims Act, the report must be provided to the Government within thirty (30) days
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violation.²⁹ Prompt reporting will demonstrate the clinical laboratory's good faith and willingness to work with Governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (e.g., penalties, assessments, and exclusion), if the reporting provider becomes the target of an OIG investigation.³⁰

When reporting misconduct to the Government, a clinical laboratory should provide all evidence relevant to the potential violation of applicable federal or state law(s) and potential cost impact. The compliance officer, under advice of counsel, and with guidance from the Governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, the compliance officer should be required to notify the appropriate Governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable health care programs or their beneficiaries. If the investigation ultimately indicates that criminal or civil

²⁸(...continued)

after the date when the laboratory first obtained the information. 31 U.S.C. § 3729(a).

²⁹The OIG believes that some violations may be so serious that they warrant immediate notification to Governmental authorities, prior to, or simultaneous with, commencing an internal investigation, e.g., if the conduct: (1) is a clear violation of criminal law; (2) has a significant adverse effect on the quality of care provided to program beneficiaries (in addition to any other legal obligations regarding quality of care); or (3) indicates evidence of a systemic failure to comply with applicable laws, an existing corporate integrity agreement, or other standards of conduct, regardless of the financial impact on federal health care programs.

³⁰The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude a health care provider from program participation pursuant to 42 U.S.C. § 1320a-7(b)(7) for violations of various fraud and abuse laws. See 62 Fed. Reg. 67,392 (12/24/97).

violations may have occurred, the appropriate federal and state officials³¹ should be notified immediately.

As previously stated, the clinical laboratory should take appropriate corrective action, including the imposition of proper disciplinary action, and prompt identification and restitution of any overpayment to the affected payor. In cases where potential fraud or violations of the False Claims Act are involved payment should be made as part of discussions with law enforcement. Failure to repay overpayments within a reasonable period of time could be interpreted as an intentional attempt to conceal the overpayment from the Government, thereby establishing an independent basis for a criminal violation with respect to the clinical laboratory, as well as any individuals who may have been involved.³² For this reason, clinical laboratory compliance programs should emphasize that overpayments obtained from Medicare or other federal health care programs should be promptly returned to the payor that made the erroneous payment. Section F details the information which should be provided to the contractor when making a repayment.

³¹ Appropriate federal and state authorities include the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in the clinical laboratory's district, and the investigative arms for the agencies administering the affected federal or state health care programs, such as the state Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, and the Offices of Inspector General of the Department of Health and Human Services, the Department of Veterans Affairs and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

³² See 42 U.S.C. § 1320a-7b(a)(3).

III. CONCLUSION

Through this document, the OIG has attempted to provide a foundation for development of an effective and cost-efficient clinical laboratory compliance program. As previously stated, however, each program must be tailored to fit the needs and resources of an individual clinical laboratory, depending upon its particular corporate structure, mission, size and employee composition. The statutes, regulations and guidelines of the federal and state health insurance programs, as well as the policies and procedures of the private health plans, should be integrated into every clinical laboratory's compliance program.

The OIG recognizes that the health care industry in this country, which reaches millions of beneficiaries and expends about a trillion dollars annually, is constantly evolving. As stated throughout this guidance, compliance is a dynamic process that helps to ensure that clinical laboratories and other health care providers are better able to fulfill their commitment to ethical behavior, as well as meet the changes and challenges being imposed upon them by Congress and private insurers. Ultimately, it is OIG's hope that a voluntarily created compliance program will enable clinical laboratories to meet their goals, improve the quality of services and control of claims submission, and substantially reduce fraud, waste and abuse, as well as the cost of health care to federal, state and private health insurers.